

5.0 510(k) Summary

510(k) Number: k121003

DEC 21 2012

Device Name: PLEX-ID Flu

Purpose of the Submission: The purpose of this 510(k) is to gain clearance to market the PLEX-ID Flu (List No. 05N21) assay.

5.1 Official Correspondent to the File

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5.2 Date of Preparation

March 30, 2012

5.3 Sponsor

Abbott Molecular Inc. is sponsor of the PLEX-ID Flu (List No. 05N21) 510(k) submission.

5.4 Intended Use

The PLEX-ID Flu assay is a qualitative nucleic acid *in vitro* diagnostic test intended for the detection and differentiation of influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal) and influenza B viral nucleic acids in nasopharyngeal swab specimens from patients symptomatic for respiratory tract infection. The PLEX-ID Flu assay is intended for use on the PLEX-ID System (version 1.2) as an aid in the diagnosis of influenza infection in conjunction with clinical and epidemiological information. This assay is not intended to detect influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

5.5 Trade Name

PLEX-ID Flu (List No. 05N21)

5.6 Common Name

Nucleic acid assay for the detection of influenza virus

5.7 Classification Name and Regulation

- Regulation Number: 21 CFR 866.3980
- Classification Name: Respiratory viral panel multiplex nucleic acid assay

5.8 Predicate Devices

- Prodesse ProFLU+™ assay (K073029)
- Prodesse ProFAST+™ assay (K101855)

5.9 Device Description

The PLEX-ID Flu assay consists of the following kits:

- PLEX-ID Flu Amplification Kit (List No. 05N21-91)
- PLEX-ID Flu Control Kit (List No. 05N21-80)

The PLEX-ID Flu assay is a qualitative in vitro diagnostic test used for the detection and identification of influenza A and B viruses directly from human samples. First, nucleic acids are extracted from samples. Nucleic acids are then amplified via a reverse transcription polymerase chain reaction (RT-PCR). The PCR products are subsequently desalting and analyzed in a mass spectrometer to determine the base composition of the PCR products. Analysis of the base composition of PCR products is used to determine identity by comparison to a proprietary database. Desalting, mass spectrometry and data analysis are conducted on the PLEX-ID Analyzer. Reported results include an identification of influenza virus species and subtypes of influenza A virus.

5.10 Background on Influenza

Influenza is a respiratory virus that can cause mild to severe disease, and at times can lead to death. Every year in the United States, on average 5% to 20% of the population gets the flu; more than 200,000 people are hospitalized from flu complications, and about 3,000 to 49,000 people die from flu-related causes. Some people, such as adults 65 years or older, young children, and people with certain health conditions, are at high risk for serious flu complications.^{1,2}

There are two main types of influenza (flu) virus, A and B, which are responsible for seasonal epidemics of flu amongst humans. Influenza A viruses are divided into subtypes based on two proteins on the surface of the virus: hemagglutinin (H) and neuraminidase (N). The common Influenza A virus subtypes found in people are A (H1N1) and A (H3N2). In April of 2009, a new strain of Influenza A emerged. On June 11, 2009 WHO classified the 2009 H1N1 Influenza A strain as the cause of a phase 6 pandemic.³

5.11 Technological Characteristics of the Device as Compared to the Predicate

These devices are similar in that they are designed to prepare nucleic acids for amplification, amplify specific influenza sequences, detect the amplified products, and report qualitative results.

The primary similarities and differences between the PLEX-ID Flu assay and the predicate devices are shown in Table 1.

Table 1
Similarities and Differences Between PLEX-ID Flu and Predicate Devices

<u>Feature</u>	<u>Current Application</u>			<u>Predicate Devices</u>
	<u>PLEX-ID Flu</u>	<u>Prodesse ProFLU+</u>	<u>Prodesse ProFAST+</u>	
510(k) Number	K121003	K073029	K101855	
Regulation No. and Product Code	21 CFR 866.3980 OEP, OCC, OQW, OTA	21 CFR 866.3980 OCC	21 CFR 866.3332 OQW	

Feature	Current Application	PLEX-ID Flu	ProFlex™+ Assay						
Feature	Current Application	PLEX-ID Flu	ProFlex™+ Assay						
Intended Use	The PLEX-ID Flu assay is a qualitative nucleic acid <i>in vitro</i> diagnostic test intended for the detection and differentiation of influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal) and influenza B viral nucleic acids in nasopharyngeal swab specimens from patients symptomatic for respiratory tract infection. The PLEX-ID Flu assay is intended for use on the PLEX-ID System (version 1.2) as an aid in the diagnosis of influenza infection in conjunction with clinical and epidemiological information. This assay is not intended to detect influenza C virus.	The ProFlex™+ Assay is a multiplex Real-Time PCR (RT-PCR) <i>in vitro</i> diagnostic test for the rapid and qualitative detection and discrimination of seasonal Influenza A/H1, seasonal Influenza A/H3 and 2009 H1N1 Influenza viral nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. This assay targets conserved regions of the Hemagglutinin (HA) gene for seasonal Influenza A/H1, seasonal Influenza A/H3 and 2009 H1N1 Influenza Virus, respectively. This assay is not intended to detect Influenza B or Influenza C Viruses.	The ProFlex™+ Assay is a multiplex Real-Time PCR (RT-PCR) <i>in vitro</i> diagnostic test for the rapid and qualitative detection and discrimination of influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal) and influenza B viral nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. This test is intended for use to aid in the differential diagnosis of Influenza A, Influenza B and RSV viral infections in humans and is not intended to detect Influenza C.	The ProFlex™+ Assay is a multiplex Real-Time PCR (RT-PCR) <i>in vitro</i> diagnostic test for the rapid and qualitative detection and discrimination of influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal) and influenza B viral nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. 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Feature	Current Application			Predicate Devices
	PLEX-ID Flu	Prodesse ProFLU+	Prodesse ProFAST+	
Assay Type	<ul style="list-style-type: none"> Qualitative 	<ul style="list-style-type: none"> Qualitative 	<ul style="list-style-type: none"> Qualitative 	<ul style="list-style-type: none"> Qualitative
Analyte Targets	<ul style="list-style-type: none"> influenza genus → Primer pair 2798 targets polymerase PB1 influenza A → Primer Pair 1266 targets nucleoprotein influenza A → Primer Pair 1279 targets matrix protein influenza A → Primer Pair 1287 polymerase A protein influenza A → Primer Pair 2775 non-structural protein 1, NS1 influenza A → Primer Pair 1259 targets polymerase, PB influenza A H1N1 (2009) → Primer Pair 5101 targets hemagglutinin, HA influenza A H1N1 (2009) → Primer Pair 4998 targets neuraminidase, NA influenza B → Primer Pair 1261 targets polymerase, PB2 	<ul style="list-style-type: none"> Influenza A Virus → Matrix Respiratory Syncytial Virus A → Polymerase Respiratory Syncytial Virus B → Polymerase Influenza B Virus → Non-structural NS1 and NS2 	<ul style="list-style-type: none"> Seasonal H1 Influenza A → Hemagglutinin Seasonal H3 Influenza A → Hemagglutinin 2009 H1N1 Influenza Virus → Hemagglutinin 	<ul style="list-style-type: none"> Seasonal H1 Influenza A → Hemagglutinin Seasonal H3 Influenza A → Hemagglutinin 2009 H1N1 Influenza Virus → Hemagglutinin
Input Sample Types	<ul style="list-style-type: none"> nasopharyngeal swab 	<ul style="list-style-type: none"> nasopharyngeal swab 	<ul style="list-style-type: none"> nasopharyngeal swab 	<ul style="list-style-type: none"> nasopharyngeal swab

<u>Feature</u>	<u>Current Application</u>	<u>Predicate Devices</u>
Sample Collection	<p>PLEX-ID Flu</p> <ul style="list-style-type: none"> Immediately following collection of the sample from the patient, place the swab into a tube containing 3 mL of viral transport media. Place on ice or refrigerate. Samples for the PLEX-ID Flu assay may be collected in: • Micro TestTM M4R Viral Transport Medium • Micro TestTM M5R Viral Transport Medium • Micro TestTM M6R Viral Transport Medium • Micro TestTM M4RTR Viral Transport Medium • Copan Universal Transport Medium • BD Universal Viral Transport Medium 	<p>Prodesse ProFLU+</p> <ul style="list-style-type: none"> Following collection, place the swab into a tube containing 2 to 3 mL of viral transport medium (Rемel M4, M4RT, M5, M6; Copan UTM; or Becton Dickinson UVT). When starting from purified nucleic acid samples that have been previously processed for testing with the ProFLU+ Assay, begin with the RT-PCR reaction. <p>Prodesse ProFAST+</p> <ul style="list-style-type: none"> Following collection, place the swab into a tube containing 2 to 3 mL of viral transport medium (Rемel M4, M4RT, M5, M6; Copan UTM; or Becton Dickinson UVT). When starting from purified nucleic acid samples that have been previously processed for testing with the ProFLU+ Assay, begin with the RT-PCR reaction.
Input Sample Volume	<ul style="list-style-type: none"> • 300 µL 	<ul style="list-style-type: none"> • 180 µL • 180 µL

<u>Feature</u>	<u>Current Application</u>	<u>Predicte Devices</u>
<u>Principles of the Procedure</u>	<p>PLEX-ID Flu</p> <ul style="list-style-type: none"> Automated sample to extraction plate Automated nucleic acid extraction Automated transfer of sample eluate to PCR Plate Automated PCR amplification Automated desalting of PCR products Mass Spectrometry analysis converts mass of PCR products to base composition Base composition signature from multiple PCR products is then used to identify the influenza virus species and subtype <p>Prodesse ProFLU+</p> <ul style="list-style-type: none"> Automated nucleic acid isolation Manual transfer of sample eluate to PCR Plate Automated PCR amplification Optical detection of stimulated fluorescence The fluorescence reader monitors real-time fluorescence during every PCR amplification cycle 	<p>Prodesse ProFAST+®</p> <ul style="list-style-type: none"> Automated nucleic acid isolation Manual transfer of sample eluate to PCR Plate Automated PCR amplification Optical detection of stimulated fluorescence The fluorescence reader monitors real-time fluorescence during every PCR amplification cycle
<u>Instrumentation Principle System Components</u>	<p>PLEX-ID System</p> <ul style="list-style-type: none"> The PLEX-ID System integrates sample preparation (PLEX-ID SP, PLEX-ID FH) with PCR amplification (PLEX-ID TC) followed by mass spectrometry analysis to generate assay results (PLEX-ID Analyzer). 	<p>Nucleic Acid Isolation instrument</p> <ul style="list-style-type: none"> Nucleic Acid isolation instrument Amplification and detection instrument <p>Nucleic Acid Isolation instrument</p> <ul style="list-style-type: none"> Nucleic Acid isolation instrument Amplification and detection instrument
<u>Sample Preparation Instrument Components</u>	<ul style="list-style-type: none"> Liquid handling and robotic manipulation platform (PLEX-ID SP, PLEX-ID FH) using the PLEX-ID Viral RNA Isolation Kit 	<p>Automated nucleic acid isolation instrument (MagNA Pure LC System using the Total Nucleic Acid Isolation (TNAI) Kit or NucliSENS easyMAG System using the Automated Magnetic Extraction Reagents)</p> <ul style="list-style-type: none"> Automated nucleic acid isolation instrument (MagNA Pure LC System using the Total Nucleic Acid Isolation (TNAI) Kit or NucliSENS easyMAG System using the Automated Magnetic Extraction Reagents)
<u>Amplification and Detection Instrument Components</u>	<ul style="list-style-type: none"> Automated PCR amplification (PLEX-ID TC) is followed by mass spectrometry analysis and influenza virus identification (PLEX-ID Analyzer) 	<ul style="list-style-type: none"> Automated PCR amplification and detection by fluorescence analysis (Cepheid SmartCycler II) Automated PCR amplification and detection by fluorescence analysis (Cepheid SmartCycler II)

<u>Feature</u>	<u>Current Application</u>	<u>Predicte Devices</u>
	<u>PLEX-ID Flu</u>	<u>ProFLU+</u>
Amplification Controls	<ul style="list-style-type: none"> Each PCR reaction well contains an Amplification Control that consists of a synthetic RNA molecule specific to the primer pairs used, but distinguishable from known target sequences. The Amplification Control serves as the internal PCR control and provides scaling information for the level of influenza RNA present in the sample. It also detects PCR inhibition, reagent failure, and process errors. 	<ul style="list-style-type: none"> Internal Control to detect PCR inhibition in individual samples and Reagent failure or process error
Amplification Enzyme Type(s)	<ul style="list-style-type: none"> DNA Polymerase Reverse Transcriptase 	<ul style="list-style-type: none"> Taq DNA Polymerase Reverse Transcriptase
Detection Procedure	<ul style="list-style-type: none"> Mass Spectrometry analysis converts mass of PCR products to base composition Base composition signature from multiple PCR products is then used to identify the influenza virus species and subtype 	<ul style="list-style-type: none"> Optical detection of stimulated fluorescence. The fluorescence reader monitors real-time fluorescence during every PCR amplification cycle.

Feature	Current Application			Predicate Devices		
	PLEX-ID Flu	ProFLU+	Prodesse ProFAST+	Prodesse ProFAST+	Prodesse ProFAST+	Prodesse ProFAST+
Limit of Detection (LOD)	<ul style="list-style-type: none"> Influenza A H1N1 (2009) (Strain A/SwineNY/02/2009 H1N1) – 1.3 × 10⁻¹ TCID₅₀/mL Influenza A H1N1 (seasonal) (Strain A/New Caledonia/20/99 H1N1) – 4.6 TCID₅₀/mL Influenza A H3N2 (seasonal) (Strain A/Wisconsin/67/05 H3N2) – 3.3 × 10² TCID₅₀/mL Seasonal Influenza B (Strain B/Panama/45/90) – 15 TCID₅₀/mL 	<ul style="list-style-type: none"> Influenza A/Port Chalmers/1/73 (H3N2) – 10¹ TCID₅₀/mL Influenza A/CA/7/04 (H3N2) – 10⁰ TCID₅₀/mL Influenza A/New Caledonia/12/99 (H1N1) – 10² TCID₅₀/mL Influenza A/WS/33 (H1N1) – 10⁰ TCID₅₀/mL Influenza B/Lee/40 – 10¹ TCID₅₀/mL Influenza B/Wisconsin/2/06 – 10⁰ TCID₅₀/mL 	<ul style="list-style-type: none"> H1N1 A/Virginia/1/06 – 5 × 10⁻¹ TCID₅₀/mL H1N1 A/Hong Kong/2652/06 – 5 × 10⁻² TCID₅₀/mL H3N2 A/Anhui/1239/05 – 1 × 10⁻¹ TCID₅₀/mL H3N2 A/California/07/04 – 5 × 10⁻¹ TCID₅₀/mL 2009 H1N1 Clinical Isolate #1 – 1 × 10² TCID₅₀/mL 2009 H1N1 Clinical Isolate #5 – 1 × 10² TCID₅₀/mL 	<ul style="list-style-type: none"> H1N1 A/Virginia/1/06 – 5 × 10⁻¹ TCID₅₀/mL H1N1 A/Hong Kong/2652/06 – 5 × 10⁻² TCID₅₀/mL H3N2 A/Anhui/1239/05 – 1 × 10⁻¹ TCID₅₀/mL H3N2 A/California/07/04 – 5 × 10⁻¹ TCID₅₀/mL 2009 H1N1 Clinical Isolate #1 – 1 × 10² TCID₅₀/mL 2009 H1N1 Clinical Isolate #5 – 1 × 10² TCID₅₀/mL 		
Assay Controls	<ul style="list-style-type: none"> Negative Control Positive Control 	<ul style="list-style-type: none"> Negative Control Positive Control Extraction Control 	<ul style="list-style-type: none"> Negative Control Positive Control Extraction Control 	<ul style="list-style-type: none"> Negative Control Positive Control Extraction Control 	<ul style="list-style-type: none"> Negative Control Positive Control Extraction Control 	<ul style="list-style-type: none"> Negative Control Positive Control Extraction Control
Results Reporting	<ul style="list-style-type: none"> The PLEX-ID Flu assay reports results for both influenza A and influenza B in separate sections of the report. The influenza A report can show the following under Detected Microbe: <ul style="list-style-type: none"> 2009 (Pandemic) H1N1 Influenza A Seasonal H1N1 Influenza A Seasonal H3N2 Influenza A Other influenza A Not Detected The influenza B report can show the following under Detected Microbe: <ul style="list-style-type: none"> Seasonal H1N1 Influenza B Not detected 	<ul style="list-style-type: none"> Influenza A result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H1 Influenza B result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H3 “Unresolved” – PCR inhibition or reagent failure. 	<ul style="list-style-type: none"> H1 result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H1 H3 result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H3 2009 H1N1 result of either “POS” for positive or “NEG” for negative for 2009 H1N1 Influenza RNA “Unresolved” – PCR inhibition or reagent failure. 	<ul style="list-style-type: none"> Influenza A result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H1 Influenza B result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H3 “Unresolved” – PCR inhibition or reagent failure. 	<ul style="list-style-type: none"> Influenza A result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H1 Influenza B result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H3 “Unresolved” – PCR inhibition or reagent failure. 	<ul style="list-style-type: none"> Influenza A result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H1 Influenza B result of either “POS” for positive or “NEG” for negative for Seasonal Influenza A/H3 “Unresolved” – PCR inhibition or reagent failure.

<u>Feature</u>	<u>Current Application</u>	<u>Predicte Devices</u>
	<u>PLEX-ID Flu</u>	<u>Prodesse ProFLU+</u>
		<u>Prodesse ProFAST+</u>
Drug / Compound Interference	<ul style="list-style-type: none"> Samples containing FluMist® may cause false positive results in the assay. FluMist is an intranasal vaccine that contains live attenuated influenza virus that is detected by the PLEX-ID Flu assay. No interference was detected from other common cold medicines or mucin 	<ul style="list-style-type: none"> An interference study evaluating potentially interfering common cold medications was not performed.
Reagents and Controls Storage Conditions	<ul style="list-style-type: none"> Frozen (-10°C or colder) 	<ul style="list-style-type: none"> -70°C or colder -70°C or colder

5.12 Performance Characteristics

5.12.1 Expected Values

The clinical performance of the PLEX-ID Flu assay on the PLEX-ID System was established using nasopharyngeal (NP) swab specimens prospectively collected from two U.S. clinical sites and three specimen suppliers from September 2009 through June 2010. A total of 1287 prospective NP swab specimens were collected for the PLEX-ID Flu clinical study. Of the 1287, five specimens were excluded: duplicate specimens were collected from two subjects (the second specimen from each subject was excluded from the analysis), one specimen from a subject who did not meet the inclusion criteria, and two specimens had an invalid PLEX-ID Flu result, for a total of 1282 included specimens. The prevalence of influenza A 2009 H1N1 decreased significantly during the collection period, consequently, there were only 37 positive influenza A 2009 H1N1, 4 positive influenza A H1N1 (seasonal), 50 positive influenza A H3N2 (seasonal), and 24 positive influenza B specimens among the 1282 specimens. Prevalence rates and demographics are presented in Table 2 and Table 3, respectively, for four of the five sites that provided prospectively collected specimens. No demographic information was available from supplier Site 3 (N=199) and one subject from clinical Site 1.

Table 2
Influenza Prevalence Rate – Prospectively Collected Specimens

Number of Positives by the PLEX-ID Flu Assay (Observed Prevalence Rate)					
Age Group	N	2009 H1N1	Seasonal H1N1	Seasonal H3N2	Influenza B
< 2 years	202	3 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2 to 5 years	46	1 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
6 to 11 years	20	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 to 18 years	49	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
19 to 64 years	730	18 (2.5%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
> 65 years	35	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unknown*	200	14 (7.0%)	4 (2.0%)	50 (25.0%)	23 (11.5%)
Total	1282	37 (2.9%)	4 (0.3%)	50 (3.9%)	24 (1.9%)

* Demographic information was unavailable.

Table 3
Subject Demographics – Prospectively Collected Specimens

Gender/Age	Number of Subjects (%)
Female	603 (47.0%)
Male	479 (37.4%)
Unknown*	200 (15.6%)
Total	1282 (100.0%)

* Demographic information was unavailable.

5.12.2 Clinical Performance

5.12.2.1 Prospective Clinical Study

Clinical performance of the PLEX-ID Flu assay was assessed by testing nasopharyngeal (NP) swab specimens from subjects presenting with symptoms of influenza-like illness.

Prospectively collected clinical specimens were tested at three sites. All specimens were tested with an assay FDA cleared for the detection and discrimination of influenza A virus, influenza B virus, and Respiratory Syncytial virus nucleic acids isolated and

purified from NP swab specimens obtained from symptomatic patients (Comparator 1). Specimens with a positive influenza A test result went on for further testing with Comparator 2, an assay FDA cleared for the detection and discrimination of influenza A virus subtypes [influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal)] from nucleic acids isolated and purified from NP swab specimens. Aliquots from the same specimens were tested with the PLEX-ID Flu assay. For each subtype of influenza A [H1N1 (2009), H1N1 (seasonal), H3N2 (seasonal)], the point estimate for positive percent agreement (PPA) and negative percent agreement (NPA) was calculated. PCR followed by bi-directional sequencing was used to test discrepant samples between Comparator 1 and Comparator 2, Comparator 1 vs. PLEX-ID Flu, and Comparator 2 vs. PLEX-ID Flu. The results from bi-directional sequence testing were not used to calculate the positive percent agreement and negative percent agreement of the PLEX-ID Flu assay.

Of the 1282 specimens included in the study, 6 were unresolved by Comparator 1 and were excluded, resulting in 1276 specimens included in the final analysis.

A total of 90 unique specimens were influenza A positive by Comparator 1 and 1186 were negative. All 90 specimens were tested by Comparator 2 to determine influenza A subtypes [influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal)]. From these 90 unique specimens, 6 were negative for all three subtypes by Comparator 2. The remaining 84 specimens generated a total of 88 positive results. Four specimens generated two different subtype results each by Comparator 2. For one of these four specimens, Comparator 2 assay reported both H1N1 and H3N2 while the PLEX-ID Flu assay reported an H1N1 (seasonal) result. For the remaining 3 specimens, Comparator 2 reported both H3N2 and H1N1, whereas the PLEX-ID Flu assay reported H3N2 (seasonal). These 88 positive results comprised 32 influenza A H1N1 (2009), 7 influenza A H1N1 (seasonal) positive, and 49 influenza A H3N2 (seasonal) positive results.

From the 1287 prospective NP swab specimens collected for this study and tested, 98.7% (1285/1302) of PLEX-ID assays results generated were valid.

The comparison of the PLEX-ID Flu assay and Comparator 2 results for influenza A H1N1 (2009) are shown in Table 4, influenza A H1N1 (seasonal) in Table 5, and influenza A H3N2 (seasonal) in Table 6.

Table 4
PLEX-ID Flu
Influenza A H1N1 (2009) Specimen Testing

	Comparator 2 Positive	Comparator ^a Negative	Total
PLEX-ID Flu Positive	32	5 ^b	37
PLEX-ID Flu Negative	0	1239	1239
Total	32	1244	1276
Percent Agreement (95% CI)	Positive Percent Agreement 100.0% (32/32) (89.3%, 100.0%)	Negative Percent Agreement 99.6% (1239/1244) (99.1%, 99.8%)	

^aNegative for influenza A by Comparator 1 (and therefore untested by Comparator 2) or positive for influenza A by Comparator 1 and negative by Comparator 2 reflex testing for influenza A H1N1 (2009).

^bFive samples were negative for influenza A 2009 H1N1 by Comparator 2; three samples were positive by bi-directional sequence analysis for 2009 H1N1, one had insufficient sample volume for bi-directional sequence analysis, and 2009 H1N1 nucleic acid was not detected by bi-directional sequence analysis in one sample.

Table 5
PLEX-ID Flu
Influenza A H1N1 (Seasonal) Specimen Testing

	Comparator 2 Positive	Comparator ^a Negative	Total
PLEX-ID Flu Positive	4	0	4
PLEX-ID Flu Negative	3 ^b	1269	1272
Total	7	1269	1276
Percent Agreement (95% CI)	Positive Percent Agreement 57.1% (4/7) (25.0%, 84.2%)	Negative Percent Agreement 100.0% (1269/1269) (99.7%, 100.0%)	

^aNegative for influenza A by Comparator 1 (and therefore untested by Comparator 2) or positive for influenza A by Comparator 1 and negative by Comparator 2 reflex testing for influenza A H1N1 (Seasonal).

^bA/H1 nucleic acids were not detected by bi-directional sequence analysis in these three samples.

Table 6
PLEX-ID Flu
Influenza A H3N2 (Seasonal) Specimen Testing

	Comparator 2 Positive	Comparator ^a Negative	Total
PLEX-ID Flu Positive	48	2 ^b	50
PLEX-ID Flu Negative	1 ^c	1225	1226
Total	49	1227	1276
Percent Agreement (95% CI)	Positive Percent Agreement 98.0% (48/49) (89.3%, 99.6%)	Negative Percent Agreement 99.8% (1225/1227) (99.4%, 100.0%)	

^aNegative for influenza A by Comparator 1 (and therefore untested by Comparator 2) or positive for influenza A by Comparator 1 and negative by Comparator 2 reflex testing for influenza A H3N2 (Seasonal).

^bTwo samples were negative for influenza A by Comparator 1 and were not reflexed to Comparator 2 for subtype determination, but the samples were positive by bi-directional sequence analysis for A/H3.

^cA/H3 nucleic acid was not detected by bi-directional sequence analysis in this sample.

A total of 22 positive specimens were obtained for influenza B. The positive percent agreement and negative percent agreement were calculated. The results of the PLEX-ID Flu compared to Comparator 1 for the detection of influenza B are shown in Table 7. Bi-directional sequence analysis was not performed for discordant influenza B specimens.

Table 7
PLEX-ID Flu
Influenza B Specimen Testing

	Comparator 1 Positive	Comparator 1 Negative	Total
PLEX-ID Flu Positive	22	2	24
PLEX-ID Flu Negative	0	1252	1252
Total	22	1254	1276
Percent Agreement (95% CI)	Positive Percent Agreement 100.0% (22/22) (85.1%, 100.0%)	Negative Percent Agreement 99.8% (1252/1254) (99.4%, 100.0%)	

5.12.2.2 Retrospective Specimen Testing

Due to the decreased prevalence of influenza A 2009 H1N1 and the absence of influenza A seasonal H1N1 and H3N2, the prospectively collected specimen population was supplemented with pre-selected banked specimens that were collected in February 2008, and from January 2009 through March 2009, and left over archived specimens collected from April 2009 through December 2009.

A total of 1378 retrospective specimens were tested. Of these specimens, 1341 were included in the analysis (the remaining 37 were excluded either due to unavailable results for the PLEX-ID Flu assay or Comparator 1 assay, duplicate subjects, or failure to meet subject inclusion criteria).

Of the 1341 retrospective specimens, 634 were influenza A positive and 707 were negative by Comparator 1. All 634 positive specimens were tested to determine influenza A subtype (influenza A 2009 H1N1, influenza A (seasonal) H1N1, influenza A

(seasonal) H3N2). Two specimens were unresolved by Comparator 2 and, therefore, excluded, resulting in 1339 total specimens in the analysis. Fifty-four of the 634 Comparator 1 influenza A positive specimens were negative for all three subtypes by Comparator 2 and were included as Comparator negative specimens. Consequently, 578 positive results were included in the analysis: 548 influenza A H1N1 (2009), 28 influenza A H1N1 (seasonal), and 2 influenza A H3N2 (seasonal).

From the 1378 retrospective NP swab specimens tested in this study, 93.4% (1368/1464) of PLEX-ID assays results generated were valid.

The comparison of the PLEX-ID Flu and Comparator 2 results for influenza A H1N1 (2009) are shown in Table 8, influenza A H1N1 (seasonal) in Table 9, and influenza A H3N2 (seasonal) in Table 10.

The following analysis was performed on the leftover archived and pre-selected banked specimens.

Table 8
PLEX-ID Flu
Influenza A H1N1 (2009) Specimen Testing

	Comparator 2 Positive	Comparator ^a Negative	Total
PLEX-ID Flu Positive	538	45 ^b	583
PLEX-ID Flu Negative	10 ^c	746	756
Total	548	791	1339
Percent Agreement (95% CI)	Positive Percent Agreement 98.2% (538/548) (96.7%, 99.0%)	Negative Percent Agreement 94.3% (746/791) (92.5%, 95.7%)	

^aNegative for influenza A by Comparator 1 (and therefore untested by Comparator 2) or positive for influenza A by Comparator 1 and negative by Comparator 2 reflex testing for influenza A H1N1 (2009).

^b41 samples were positive by bi-directional sequence analysis for 2009 H1N1, 1 was unresolved, 2 had insufficient sample volume for bi-directional sequence analysis, and H1N1(2009) nucleic acid was not detected in one sample.

^cA/H1N1 (2009) was detected in 8 samples by bi-directional sequence analysis.

Table 9
PLEX-ID Flu
Influenza A H1N1 (Seasonal) Specimen Testing

	Comparator 2 Positive	Comparator ^a Negative	Total
PLEX-ID Flu Positive	27	0	27
PLEX-ID Flu Negative	1 ^b	1311	1312
Total	28	1311	1339
Percent Agreement (95% CI)	Positive Percent Agreement 96.4% (27/28) (82.3%, 99.4%)	Negative Percent Agreement 100.0% (1311/1311) (99.7%, 100.0%)	

^aNegative for influenza A by Comparator 1 (and therefore untested by Comparator 2) or positive for influenza A by Comparator 1 and negative by Comparator 2 reflex testing for influenza A H1N1 (Seasonal).

^bA/H1 nucleic acid was not detected by bi-directional sequence analysis in this sample.

Table 10
PLEX-ID Flu
Influenza A H3N2 (Seasonal) Specimen Testing

	Comparator 2 Positive	Comparator ^a Negative	Total
PLEX-ID Flu Positive	2	0	2
PLEX-ID Flu Negative	0	1337	1337
Total	2	1337	1339
Percent Agreement (95% CI)	Positive Percent Agreement 100.0% (2/2) (34.2%, 100.0%)	Negative Percent Agreement 100.0% (1337/1337) (99.7%, 100.0%)	

^aNegative for influenza A by Comparator 1 (and therefore untested by Comparator 2) or positive for influenza A by Comparator 1 and negative by Comparator 2 reflex testing for influenza A H3N2 (Seasonal).

A total of 28 positive specimens were obtained for influenza B. The positive percent agreement and negative percent agreement were calculated. The comparison results of the PLEX-ID Flu and Comparator 1 to detect influenza B are shown in Table 11. Bi-directional sequence analysis was not performed for discordant influenza B specimens.

Table 11
PLEX-ID Flu
Influenza B Specimen Testing

	Comparator 1 Positive	Comparator 1 Negative	Total
PLEX-ID Flu Positive	26	1	27
PLEX-ID Flu Negative	2	1312	1314
Total	28	1313	1341
Percent Agreement (95% CI)	Positive Percent Agreement 92.9% (26/28) (77.4%, 98.0%)	Negative Percent Agreement 99.9% (1312/1313) (99.6%, 100.0%)	

5.12.2.3 Other Clinical Supportive Data

Not applicable.

5.12.2.4 Clinical Cut-Off

Not applicable.

5.12.3 Summary of Nonclinical Studies

5.12.4 Limit of Detection

The limit of detection (LOD) for the PLEX-ID Flu assay was determined by testing quantitated influenza strains diluted in negative nasopharyngeal swab matrix. Twenty replicates of the following were tested: influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal), and influenza B. The LOD was defined as the lowest influenza concentration at which $\geq 95\%$ of replicates tested positive. The results are presented in Table 12.

Table 12
PLEX-ID Flu
Limit of Detection (LOD)

Influenza	Limit of Detection (TCID ₅₀ /mL)
influenza A H1N1 (2009)	1.3×10^{-1}
influenza A H1N1 (seasonal)	4.6×10^0
influenza A H3N2 (seasonal)	3.3×10^2
influenza B	1.5×10^1

5.12.4.1 Reproducibility

The reproducibility of the PLEX-ID Flu assay was evaluated at 3 clinical sites.

Reproducibility was assessed using a nine member panel of contrived samples that included a negative member, low positive panel members targeted near the assay LOD and moderate positive panel members targeted at approximately 2 to 3 times the LOD for influenza B and the 3 influenza A subtypes detected by the assay. Samples were tested in replicates of 4 with one replicate each of the positive and negative control per batch. Two (2) batches were run per day and each was run by a different operator with 2 operators per site. The study was designed to allow for a total of 120 results for each panel member over 5 days of testing. The results are presented in Table 13.

Table 13
PLEX-ID Flu
Reproducibility Study

Panel Member Description	Correct Results/Number Tested (% Agreement)			
	Site 1	Site 2	Site 3	Total of All Sites (95% CI)
Negative	40/40 (100.0%)	40/40 (100.0%)	40/40 (100.0%)	120/120 (100.0%) (96.9%, 100.0%)
influenza A H1N1 (2009) Low Positive	40/40 (100.0%)	39/39 ^a (100.0%)	38/40 (95.0%)	117/119 ^a (98.3%) (94.1%, 99.5%)
influenza A H1N1 (2009) Moderate Positive	40/40 (100.0%)	40/40 (100.0%)	40/40 (100.0%)	120/120 (100.0%) (96.9%, 100.0%)
influenza A H1N1 (seasonal) Low Positive	39/40 (97.5%)	40/40 (100.0%)	39/40 (97.5%)	118/120 (98.3%) (94.1%, 99.5%)
influenza A H1N1 (seasonal) Moderate Positive	40/40 (100.0%)	40/40 (100.0%)	40/40 (100.0%)	120/120 (100.0%) (96.9%, 100.0%)
influenza A H3N2 (seasonal) Low Positive	40/40 (100.0%)	40/40 (100.0%)	39/39 ^a (100.0%)	119/119 ^a (100.0%) (96.9%, 100.0%)
influenza A H3N2 (seasonal) Moderate Positive	39/40 (97.5%)	40/40 (100.0%)	40/40 (100.0%)	119/120 (99.2%) (95.4%, 99.9%)
influenza B Low Positive	40/40 (100.0%)	39/39 ^a (100.0%)	39/40 (97.5%)	118/119 ^a (99.2%) (95.4%, 99.9%)
influenza B Moderate Positive	40/40 (100.0%)	40/40 (100.0%)	39/40 (97.5%)	119/120 (99.2%) (95.4%, 99.9%)

^aMissing replicate due to instrument error.

5.12.4.2 Within Laboratory Precision

Within laboratory precision was determined by testing all nine members of the reproducibility panel in duplicate in two runs per day for a total of twelve days. Each run contained the assay positive and negative controls for a total of 20 samples per run. Multiple PLEX-ID Flu assay lots were used in the study. The results are presented in Table 14.

Table 14
PLEX-ID Flu
Within Laboratory Precision

Panel Member Description	Correct Results/Number Tested (% Agreement)	95% Confidence Interval
Negative	48/48 (100%)	(93%, 100%)
influenza A H1N1 (2009) Low Positive	48/48 (100%)	(93%, 100%)
influenza A H1N1 (2009) Moderate Positive	48/48 (100%)	(93%, 100%)
influenza A H1N1 (seasonal) Low Positive	48/48 (100%)	(93%, 100%)
influenza A H1N1 (seasonal) Moderate Positive	48/48 (100%)	(93%, 100%)
influenza A H3N2 (seasonal) Low Positive	48/48 (100%)	(93%, 100%)
influenza A H3N2 (seasonal) Moderate Positive	48/48 (100%)	(93%, 100%)
influenza B Low Positive	48/48 (100%)	(93%, 100%)
influenza B Moderate Positive	48/48 (100%)	(93%, 100%)

5.12.4.3 Cross-Reactivity

The effect of 34 common respiratory microbes on the PLEX-ID Flu assay was evaluated. Negative samples and samples containing influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal), and influenza B were tested. No interference in the performance of the PLEX-ID Flu assay was observed in the presence of the potential cross-reactants shown in Table 15 for all positive and negative samples tested.

Table 15
PLEX-ID Flu
Cross-Reactivity

Microbe	Target Spike Concentration
<i>Bordetella pertussis</i>	10^6 CFU/mL
<i>Chlamydia pneumoniae</i>	10^6 CFU/mL
<i>Corynebacterium sp.</i>	10^6 CFU/mL
<i>Escherichia coli</i>	10^6 CFU/mL
<i>Haemophilus influenzae</i>	10^6 CFU/mL
<i>Lactobacillus sp.</i>	10^6 CFU/mL
<i>Legionella pneumophila</i>	10^6 CFU/mL
<i>Moraxella catarrhalis</i>	10^6 CFU/mL
<i>Mycobacterium tuberculosis avirulent</i>	10^6 genomes/mL
<i>Mycoplasma pneumoniae</i>	10^6 CFU/mL
<i>Neisseria meningitidis</i>	10^6 CFU/mL
<i>Neisseria sp.</i>	10^5 CFU/mL
<i>Pseudomonas aeruginosa</i>	10^6 CFU/mL
<i>Staphylococcus aureus</i>	10^6 CFU/mL
<i>Staphylococcus epidermidis</i>	10^6 CFU/mL
<i>Streptococcus pneumoniae</i>	10^6 CFU/mL
<i>Streptococcus pyogenes</i>	10^6 CFU/mL

Microbe	Target Spike Concentration
<i>Streptococcus salivarius</i>	10^5 CFU/mL
Adenovirus Type 1	10^5 TCID ₅₀ /mL
Adenovirus Type 7	10^5 TCID ₅₀ /mL
Human coronavirus OC 43	10^4 TCID ₅₀ /mL
Human coronavirus OC229E	10^5 TCID ₅₀ /mL
Cytomegalovirus	10^5 TCID ₅₀ /mL
Enterovirus	10^5 TCID ₅₀ /mL
Epstein Barr virus	10^5 TCID ₅₀ /mL
Measles	10^5 TCID ₅₀ /mL
Human metapneumovirus	10^5 TCID ₅₀ /mL
Mumps virus	10^5 TCID ₅₀ /mL
Respiratory syncytial virus Type B	10^5 TCID ₅₀ /mL
Rhinovirus Type 1A	10^4 TCID ₅₀ /mL
Human parainfluenza Type 1	10^5 TCID ₅₀ /mL
Human parainfluenza Type 2	10^5 TCID ₅₀ /mL
Human parainfluenza Type 3	10^5 TCID ₅₀ /mL
Herpes simplex virus Type 1	10^5 TCID ₅₀ /mL

5.12.4.4 Potentially Interfering Substances

The effect of substances that may be present in nasopharyngeal swab samples for potential interference with the PLEX-ID Flu assay was evaluated. Negative samples and samples containing influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal), and influenza B were tested at concentrations approximately 2× LOD. No interference in the performance of the PLEX-ID Flu assay was observed in the presence of the potentially interfering substances shown in Table 16 for all positive and negative samples tested.

FluMist®, an intranasal vaccine that contains live attenuated influenza virus, was detected by the PLEX-ID Flu assay. Samples containing FluMist may cause false positive results in the assay.

Table 16
PLEX-ID Flu
Potentially Interfering Substances

Mucin: bovine submaxillary gland, type I-S	Boiron Sulphur iodatum
Blood (human)	Cepacol Dual Relief Sore Throat Spray
Neo-Synephrine	CVS Pharmacy Sore Throat Spray
Equaline 12-hour Nasal Spray	Cool Mint Listerine Antiseptic
Equaline Premium Saline Nasal Spray	Halls Mentho-Lyptus
Beconase	Tamiflu
Decadron	Flumadine
Nasarel	SYMMETREL
Allernaze	Relenza
Rhinocort Aqua Nasal Spray	BACTROBAN NASAL
Nasonex	Tobi
Oxymetazoline HCl	Adult Robitussin Chest Congestion
Flonase	CVS Children's Allergy Liquid Medication
Zicam	Delsym Cough Suppressant

Boiron Galphimia glauca	CVS Non-Drowsy Nasal Decongestant
Boiron Histaminum hydrochloricum	

5.12.4.5 Carryover

Sample carryover on the PLEX-ID System was evaluated using high target concentrations (1×10^5 viral genomes per mL) of influenza A and influenza B alternately loaded with negative samples in the sample rack, representing a worst-case, checkerboard configuration. Following 5 independent isolations, no positive results were reported among the 120 negative samples tested, resulting in an observed carryover rate of 0% (0/120).

5.12.4.6 Inclusivity

Multiple viral strains representing temporal and geographical diversity for each influenza type and subtype were tested with the PLEX-ID Flu assay. The samples were targeted at concentrations at approximately 2 \times LOD. The results reported for each strain tested matched the expected result in 3 out of 3 replicates, as shown in Table 17.

Table 17
PLEX-ID Flu
Inclusivity

Viral Strain	Concentration	Influenza A H1N1 (2009)	Influenza A H1N1 (seasonal)	Influenza A H3N2 (seasonal)	Influenza A Other	Influenza B
influenza A Swine H1N1 NY01 (2009 H1N1)	6.57 TCID ₅₀ /mL	+	-	-	-	-
influenza A Swine H1N1 NY02 (2009 H1N1)	1.06×10^1 TCID ₅₀ /mL	+	-	-	-	-
influenza A Swine H1N1 NY03 (2009 H1N1)	9.37 TCID ₅₀ /mL	+	-	-	-	-
influenza A/Brisbane/59/07	1.37×10^1 TCID ₅₀ /mL	-	+	-	-	-

Viral Strain	Concentration	Influenza A H1N1 (2009)	Influenza A H1N1 (seasonal)	Influenza A H3N2 (seasonal)	Influenza A Other	Influenza B
(Seasonal H1N1)						
influenza A/NewCal/20/1999 (Seasonal H1N1)	1.29×10^3 TCID ₅₀ /mL	-	+	-	-	-
influenza A/Taiwan/42/06 (Seasonal H1N1)	4.45×10^3 TCID ₅₀ /mL	-	+	-	-	-
influenza A/Solomon Islands/03/06 (Seasonal H1N1)	1.40×10^1 TCID ₅₀ /mL	-	+	-	-	-
influenza A/PR/8/34 (Seasonal H1N1)	4.02×10^4 CEID ₅₀ /mL	-	+	-	-	-
influenza A/WS/33 (Seasonal H1N1)	4.14×10^2 CEID ₅₀ /mL	-	+	-	-	-
influenza A/New Jersey/8/76 (Seasonal H1N1)	1.24×10^2 CEID ₅₀ /mL	-	+	-	-	-
influenza A/Weiss/43 (Seasonal H1N1)	3.41×10^6 CEID ₅₀ /mL	-	+	-	-	-
influenza A/FM/1/47 (Seasonal H1N1)	6.52×10^3 CEID ₅₀ /mL	-	+	-	-	-
influenza A/Mal/302/54 (Seasonal H1N1)	7.41×10^2 CEID ₅₀ /mL	-	+	-	-	-
influenza A/Port Chalmers/1/73 (Seasonal H3N2)	6.15×10^3 CEID ₅₀ /mL	-	-	+	-	-
influenza A/Hong Kong/8/68 (Seasonal H3N2)	4.12×10^4 CEID ₅₀ /mL	-	-	+	-	-
influenza A/Victoria/3/75 (Seasonal H3N2)	2.46×10^3 CEID ₅₀ /mL	-	-	+	-	-

Viral Strain	Concentration	Influenza A H1N1 (2009)	Influenza A H1N1 (seasonal)	Influenza A H3N2 (seasonal)	Influenza A Other	Influenza B
influenza A/Aichi/2/68 (Seasonal H3N2)	4.72×10^3 CEID ₅₀ /mL	-	-	+	-	-
influenza B/Lee/40	3.28×10^4 CEID ₅₀ /mL	-	-	-	-	+
influenza B/Mass/3/66	9.41×10^3 CEID ₅₀ /mL	-	-	-	-	+
influenza B/Taiwan/2/62	1.65×10^2 CEID ₅₀ /mL	-	-	-	-	+
influenza B/Hong Kong/5/72	2.63×10^4 CEID ₅₀ /mL	-	-	-	-	+
influenza B/GL/1739/54	1.56×10^3 CEID ₅₀ /mL	-	-	-	-	+
influenza B/Allen/45	1.30×10^2 CEID ₅₀ /mL	-	-	-	-	+
influenza B/Maryland/1/59	8.50 CEID ₅₀ /mL	-	-	-	-	+
influenza B/Russia/69	1.24×10^3 CEID ₅₀ /mL	-	-	-	-	+
influenza B/Florida/02/06	8.11×10^1 TCID ₅₀ /mL	-	-	-	-	+
influenza B/Malaysia/2506/04	2.07×10^1 TCID ₅₀ /mL	-	-	-	-	+

5.13 References

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3. Chan, Margaret. World now at the start of 2009 influenza pandemic, Statement to the press by WHO Director-General Dr Margaret Chan 11 June 2009: http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html. September 2012.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Abbott Laboratories
c/o Darren Clarke
1300 East Touhy Avenue
Des Plaines, Illinois, 60018

December 21, 2012

Re: k121003

Trade/Device Name: Abbott Plex-ID Flu Assay

Regulation Number: 21 CFR 866.3980

Regulation Name: Respiratory viral panel multiplex nucleic acid assay

Regulatory Class: Class II

Product Code: OCC, OEP, OQW, OTA

Dated: December 15, 2012

Received: December 17, 2012

Dear Mr. Clarke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Uwe Scherf for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

4.0 Indications of Use Statement

510(k) Number: k121003

Device Name: PLEX-ID Flu

Indications for Use for the PLEX-ID Flu:

The PLEX-ID Flu assay is a qualitative nucleic acid *in vitro* diagnostic test intended for the detection and differentiation of influenza A H1N1 (2009), influenza A H1N1 (seasonal), influenza A H3N2 (seasonal) and influenza B viral nucleic acids in nasopharyngeal swab specimens from patients symptomatic for respiratory tract infection. The PLEX-ID Flu assay is intended for use on the PLEX-ID System (version 1.2) as an aid in the diagnosis of influenza infection in conjunction with clinical and epidemiological information. This assay is not intended to detect influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

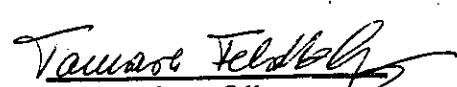
Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(Per 21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K121003